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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
03/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/524,104	SVEINSSON, BIRKIR	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,15 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 15 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 12/23/2008 has been entered.

2. Applicant's amendment, filed 02/29/2008, has been entered.

Claims 4, 6-14, 16-17 and 21-22 have been canceled.

Claims 1-3, 5, 15 and 18-20 are pending and currently under examination as they read on a method of treating or remedying psoriasis comprising administering a CGRP antagonist wherein the CGRP antagonist read on the elected specie, CGRP 8-37 as set forth in SEQ ID NO: 1.

3. This Action will be in response to Applicant's Arguments/Remarks, filed 12/23/2008.

The rejections of record can be found in the previous Office Action.

Priority

4. Applicant's amendment to the claims, filed 12/23/2008, has obviated the previous issues under Priority.

Sequence Compliance

5. Applicant's newly submitted Substitute Sequence Listing, filed 12/23/2008, comprising the amino acid sequence set forth in SEQ ID NO: 1 has been entered.

Claim Rejections - 35 USC § 112 second paragraph

6. The previous rejection under 35 U.S.C. 112, second paragraph, due to that SEQ ID NO: 1 has only 36 amino acids, has been withdrawn in view of Applicant's cancellation of the claims and newly submitted sequence listing of SEQ ID NO: 1 in the Amendment, filed 12/23/2008.

Claim Rejections - 35 USC § 112 first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The previous Written Description / New Matter rejection under 35 U.S.C. 112, first paragraph has been withdrawn in view of Applicant's cancellation of the claims and newly submitted sequence listing of SEQ ID NO: 1 in the Amendment, filed 12/23/2008.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, 5, 15 and 18-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Brenton ET al. (U.S. Patent 6,019,967, reference of record, see entire document).

Applicant's arguments, filed 12/23/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

In contrast to Applicant's argument that Brenton did not teach the treatment of psoriasis with a CGRP antagonist, the following is noted.

The present claims are drawn to a single method step of treating psoriasis comprising administering CGRP 8-37. Brenton et al. taught a composition comprising a CGRP antagonist, wherein the CGRP antagonist is CGRP-8-37. (see sections below)

> Briefly, the present **invention features the formulation of at least one CGRP antagonist into compositions** comprising a cosmetically, pharmaceutically or dermatologically acceptable medium, for treating sensitive skin-types, and for correcting neurogenic indications. (column 3, lines 14-18)
>
> **CGRP-8-37**, an anti-CGRP antibody, **is suitable for use according to this invention, for example, as a CGRP antagonist**. (column 3, lines 65-67)

Furthermore, Brenton et al. taught using the composition comprising the CGRP antagonist for treating psoriasis. (see section below)

> **These compositions** constitute, in particular, cleansing, protective, treatment or care creams for the face, for the hands, for the feet, for the major anatomical folds or for the body (for example day creams, night creams, makeup-removing creams, foundation creams and sun creams), makeup products such as fluid foundations, makeup-removing milks, body milks for care or protection, after-sun products in the form of milks, lotions, gels or mousses for skin care, such as cleansing or disinfecting lotions, antisun lotions, artificial tanning lotions, compositions for the bath, deodorizing compositions containing a bactericide, aftershave products (gels or lotions), hair-removing creams, compositions to counter insect bites, pain-relief compositions, compositions for treating acne, hyperseborrhoeic skin or seborrhoeic dermatitis, and compositions **for treating certain skin diseases such as** severe pruritus, rosacea, acne, leg ulcers, **psoriasis**, pustules and vibices. (column 4, lines 27-44)

Therefore, Brenton anticipates the present claims by teaching treating psoriasis with CGRP 8-37.

Given that Brenton et al. teach a method of treating psoriasis comprising administering topically or dermally CGRP 8-37 (e.g., see Abstract and column 4, in particular, line 44), the prior art anticipates the present claims. Furthermore, given that the prior art teaches the same or nearly the same CGRP 8-37, it would inherently "lack wildtype CGRP activity and binds to CGRP receptor" because the limitation is a mere inherent property of the CGRP antagonist.

It is again noted that "the standard for enablement of a prior art reference for purposes of anticipation under section102 differs from the enablement standard under 35 USC § 112" and that "anticipation does not require actual performance of

suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." (See, *Impax Laboratories Inc.*, 81 U.S.P.Q.2d 1001, 1012, citing *Novo Nordisk Pharms., Inc v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005)).

Given the clear teaching of Brenton as noted above, one of ordinary skill in the pertinent art, upon reading Brenton, would have been able to arrive at the single method step of treating psoriasis using CGRP 8-37, as claimed.

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record as it applies to amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

Conclusion

10. No claim is allowed.

11. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
March 10, 2009

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
March 12, 2009